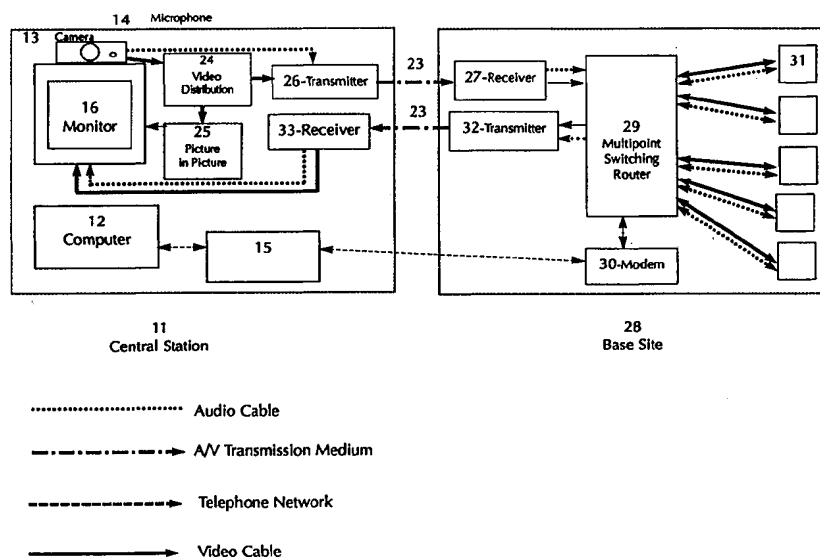




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(54) Title: SYSTEM FOR PROVIDING COMPREHENSIVE HEALTH CARE AND SUPPORT



(57) Abstract

A system and apparatus for providing comprehensive care and support to a person at a remote location (17) via interactive audio/visual communication. The system disclosed teaches aspects of a comprehensive program of care, monitoring, and support which go beyond the specific technical means for achieving interactive communication or of conducting a specific on-line electronic visit. The system of the invention is comprehensive, providing for training of personnel, education of patients or other persons being served by the system, and checks and balances for maintaining and improving the care afforded by the system. Also disclosed are apparatus and methods for protecting the privacy of individuals served by the system and means for achieving interactive communication in the most affordable manner.

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SYSTEM FOR PROVIDING COMPREHENSIVE HEALTH CARE AND SUPPORT

BACKGROUND OF THE INVENTION

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A. Field of the Invention

The present invention relates to a system for providing affordable, yet comprehensive, interactive home health care between a central station and patients at remote locations. More specifically, it concerns the apparatus, methods, software, and techniques to provide the assessment, evaluation, education, privacy, and support of an overall health care system within the sphere of interactive video home health care.

B. Description of the Prior Art

With the aging of America and the ever-increasing costs of health care, there is a surge to find alternative methods of treatment. One area that has received much attention is in providing long-term health care services to the patient in the home.

Typically, home care has been provided by the family, by non-professional support personnel, or by visiting nurses. The day-in/day-out care and support needed by a patient at home is often difficult for the family, however, because of busy work schedules, lack of proper training, or because the family member responsible for the patient's care is elderly or otherwise incapable of coping with the stress of consistent patient support. While in-home nurse visits are the preferred method of patient care, the high costs of professionally trained personnel as well as the increasing demand for such personnel due to the aging population forecasts a future where such visits would by necessity be infrequent, short, and expensive. Similar problems may be predicted for home visits by non-professional support personnel. While visits by such non-professional personnel may be less costly, allowing in theory for more frequent visits, the ever-increasing demand of an older population, logistical problems inherent in physically traveling to a patient's home, and the potential for inconsistent training of such personnel still create a situation where such visits can not match the consistent support and medical expertise offered in a hospital or nursing home environment.

In the typical home care setting, whether a patient is cared for by family or by visiting professional or non-professional health care personnel, most of the patient's day is spent alone and isolated without physical and emotional support. Such a patient must, for the most part, manage their medicines and other health care needs independently. In addition, whether the home care is undertaken by the family or through home care visits by a nurse professional, there is no one readily available to answer medical questions for the patient as they arise or provide timely feedback and education as situations develop. Finally, due to the high costs of home monitoring equipment, most patients do not have access to the necessary diagnostic equipment. Therefore, where the family has undertaken the home medical care, the patient still must be frequently transported to a doctor's office or other medical facility to achieve adequate evaluation and follow-up.

One potential solution which has received some focused attention lately is in the area of interactive telemedicine. Tests and studies begun as early as the mid 1970's have consistently shown a dramatic improvement in the physical, emotional, and psychological well being of patients receiving regular and frequent contact through some means of interactive telemedicine. Particularly noteworthy is the overall increase in patient recovery rate as a function of frequency of interaction by the patient with the doctor. In fact, some tests have indicated as much as a 50% reduction in hospital readmissions, a reduction attributed to the teleconferencing aspect of the telemedicine home visit concept. Further, where frequent and targeted education is provided to patients, the patients show dramatic improvements in their capabilities for self care and their ability to function independently.

Despite these clear advantages, the high costs of the early two-way interactive video communication models, which involved expensive transmission technology such as high speed compression and costly telephone line charges, made use of interactive audio and video cost prohibitive for the daily or even more frequent electronic visits required to provide effective in-home care to individual patients. Further, these early models failed to provide an overall system of health care to address the comprehensive needs of patients.

An early attempt at providing a means of affordable two-way communications by way of two-way community antennas, closed circuit television system, or community cable television systems is presented in U.S. Patent No. 3,668,307 to Face, *et al.* This

system, however, still requires expensive switching and controller equipment, making application to single patient sites cost prohibitive. Other drawbacks of this system are that it does not always supply a reliable signal due to limited communication band width for two-way video systems, the quality of real-time video communication or the ease of access required for daily, in home medical care.

As in the Face *et al.* Patent, other two-way communication systems proposed to date focus primarily on the hardware and communication aspects. For example, a two-way communication system between a central medical station and each of a plurality of subscriber terminals via a community antenna television CATV network is disclosed in U.S. Patent No. 5,434,611. This system involves the placement of a MCA line controller at the head end of the directional transmission lines of a standard CATV network system. Said line controller functions to facilitate simultaneous use of the communication lines for medical visits and normal television broadcasts by assigning an unused channel for such telecommunications. The MCA system further permits the automatic monitoring of patients by initiation of a signal by the central medical station or doctor's office. One drawback of such a system is in its failure to consider the concerns of patient security and confidentiality posed by a system which permits unilateral activation by the central station.

Another drawback, as previously mentioned, is that systems such as those prescribed in U.S. Patent Nos. 3,668,307 and 5,434,611 concern only the mechanics of communication of video and data across bi-directional lines and the basics of initiating such communication flow. In so doing, proper consideration has not been given to integrating the fundamental components required for an effective, comprehensive health care program into the mechanics of interactive video medicine.

Just as a school system is more than the books, the desks, the classrooms, the library, the teachers, and the class schedules, the effective home health care system is more than a collection of raw communication means and devices such as switches, cameras, microphones, and computer controller devices. As is true of any effective health care system, the comprehensive home health care system conducted via interactive video must include: a method for assessing and initiating a patient into the system; a method for individualized interaction with the patient based on the patient's personal and medical history, set protocols, physician directives, updates based on patient's past assessments, and standardized training of the medical personnel

involved; a means for assessing patient progress as judged against established parameters and learned history gleaned from evaluation of patients system-wide; a method for use of assessment data as an automatic trigger to precipitate communication with and review by a physician to provide the patient with up-to-date treatment; a means for identifying and establishing intervention from outside resources where indicated; a prescribed method and means for dealing with changes in condition and use of such data to automatically update other elements within the system; a method and means for using learned patient data and assessments to evaluate need and identify and supply proper educational support; a method for initiating data collection, storage, and directing the reporting of information; and use of reported data to assess specific patient progress as well as to evaluate and adjust overall system parameters and standards based on analysis of a collection of overall patient data and response.

While U.S. Patent No. 5,441,047 gives cursory mention to some of the aspects of an overall health care system as applied to use of interactive audio/video communication system such as on-going patient assessment, storage of data, comparison of data to known patient parameters, reporting of collected data, the ability to address patient concerns on an immediate basis, and patient education and instruction, the focus is again on the technical aspects of collecting, storing, and transmitting patient data. There is no teaching as to a method or means of incorporating these elements into a functioning remote interactive video health care system. Nor is there any teaching of the interrelationship of these elements necessary to achieve a health care system which will offer the home bound patient the same, or even enhanced, benefits of a patient in a traditional medical or nursing home facility and thus lacks a principal feature and advantage of the present invention.

Another drawback of the 5,441,047 Patent is in the area of patient confidentiality. While the inherent problems with patient confidentiality and privacy are noted, no effective solution is offered. The invention teaches a communication system where a call may be independently initiated from the central station 24 hours a day. The solution offered is a suggestion that the parties can deal with the privacy issues intrinsic to such a system by agreeing up front to allow for monitoring only during prearranged periods. Further, it is implied that concerns regarding a patient's privacy should be tempered by the fact that patients in nursing homes or other medical

institutions enjoy only minimal privacy. One of the key advantages of being able to receive treatment within one's own home, however, should be the enjoyment of increased privacy over such institutional situations. Even if prearranged times are agreed to for electronic visits as suggested in the 5,441,047 Patent, it is easy to
5 imagine a patient who has merely forgotten the time and is not prepared for the visit when the central station switches on the unit. Thus, the teachings of the 5,441,047 Patent lack another important feature and advantage of the present invention.

From the foregoing, it will be appreciated that what is needed in the art is a method and means for providing a comprehensive home health care system by means
10 of interactive audio/visual communication which is affordable; addresses a patient's privacy concerns; and offers the patient the advantages of the assessment, training, education, personal contact, support, and quality control of a traditional institutional health care system.

Accordingly, it is a primary object of the present invention to provide a fully-
15 integrated and comprehensive health care system between a patient at a remote site and medical or other professional personnel at a central location through the use of interactive audio/visual communication.

It is a further object of the present invention to provide some protection of the patient's privacy.

20 Still another object is to provide a two-way interactive audio/visual home health care system which is economical and offers the high quality, real time, full-motion video which will best simulate personal contact and, thus, provide the psychological and emotional benefits of human interaction as well as the means for enhanced medical assessment.

SUMMARY OF THE INVENTION

The present invention relates to a system for providing affordable, comprehensive, confidential, and effective health care and support by means of interactive audio/video communications between a patient or other person in need of physical, social, or
30 psychological care or monitoring located at home or other remote site and a health care practitioner, clinician, social worker, psychologist, or other such professional based at a central location. The term home health care system is intended in its broadest sense to include care systems focused on the social, physical, medical, emotional and

psychological needs of a patient. Similarly, the term patient should also be considered in the broad context of a person or client in need of support, care, monitoring, education and the like. The focus of the invention is on the assessment, interaction, training, education, quality controls, standards, protocols, and the interrelationships of these elements as they are employed in the context of an interactive audio/video health, social, or psychological care system.

Elements that comprise the basic communication package, therefore, are merely the vehicle through which the health care systems of the present invention are performed. Thus, the hardware, switches, cameras, computers, transmission means, and other such elements of the basic communication process may be accomplished by various known means using off-the-shelf technology. For instance, the establishment of communication linkages may be achieved by various transmission medium including use of community antenna systems, community cable television systems, fiber optics, satellite, radio transmission, telephone lines, or through any other mode of communication now known or yet to be implemented. A key feature of the present invention, therefore, is that the system accommodates multiple transmission mediums. Thus, as various communication services become available within a given area or to a particular patient's home, the system is capable of adapting to employ the most efficient and effective communication vehicle. Another important feature of the present invention is the ability to achieve signal transmission which is discrete in both directions, thereby accommodating privacy concerns. Further, according to the present invention, it is desirable that the transmission of audio, video, and data is accomplished through interactive full motion, real-time television or compressed video with minimal video/audio latency. In addition to providing the health care worker with an increased ability to assess the patient, such quality of transmission will also provide more of the proven benefits of personal interaction by making the electronic visit feel more life-like.

The central station includes a computer equipped with a specialized patient management software or database to facilitate patient visits, patient assessment, data management and presentation, education, and the inter-relationship of the various segments of the health care system. A monitor or other such video/audio display means is located at the central station to accommodate a video and audio display of the patient to the health care professional. Further, a communication device is provided which is capable of transmitting data to the remote location. Finally, a camera and microphone

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or other such video and audio components are mounted so as to generate a transmittable image and the voice of the health care practitioner.

The remote site where the patient is located similarly includes a television or other video/audio display device for presentation of the voice and image of the health care practitioner generated at the central station to the patient at the remote site. A camera and microphone or other such video and audio component is similarly fixed in a location to achieve a desired view and voice of the patient and for transmission to the central station during the electronic home visit. Finally, the remote site may include a communication transmission device capable of transmitting data to the central station.

The monitor at the patient's site may be modified to be capable of remote turn-on and turn-off originating from the central location and may further be adapted with a timed warning device which will alert the patient of an impending electronic visit so that the patient can take care of privacy concerns before the monitor becomes activated. Similarly, the remote patient site may include an activation device which may be used by the patient to initiate communication with the central station or other preselected site such as an emergency care facility should the need arise. Other desirable features may include a medical monitoring device which is economical, simple in construction and use, and which is capable of sensing or detecting physiological measurements such as glucose, blood pressure, respiration, and pulse, and then either immediately sending such information to the central station or storing it for future transmission. Where a particular choice of equipment or transmission means is preferred for practice of the present invention, such will be noted in the following description of the preferred embodiment.

Key to the home health care system of the present invention is in the interaction of the various features to provide a comprehensive health care system. A system is provided which begins with initial assessment and evaluation of each potential patient; extends through the treatment, on-going assessment, evaluation, response, and education of each individual patient within the system; and finally collects and analyzes the feedback from each patient and health care professional in the system individually and as a group to provide an improved system for each patient in the future.

While the following description focuses on use of the interactive comprehensive system of the present invention in the application of health or medical care, it should be appreciated that this system is also effective for other means of in-home patient or client care. For example, a social care model of the system of the present invention may be

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adopted for use with a client who may not necessarily require medical treatment or medical monitoring. In such a case, interactive electronic visits would proceed according to the present invention with some minor modification. For instance, services in such a case would typically be provided by an aide or social worker rather than by an registered nurse or other medical personnel. In this model, the client would be monitored daily, or at such other appropriate frequency, to monitor and support the client for social concerns such as being certain that they are receiving proper food, shelter, or other such social need.

Similarly, a psychiatric model of the system of the present invention would be staffed by professionals trained in psychiatry, psychology, or other mental health fields. Individual, family and group therapy sessions could be conducted via the same interactive audio/video system used in the home health care model. In addition, such patients could be monitored daily to assess their mood, oversee their medication, and provide other assessment and support.

But for a few minor changes, therefore, it should be appreciated that the overall system is applicable to many different areas with these being but a few examples. It is with this definition in mind, the following description is provided.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows the basic equipment and set-up at the central location and at the remote patient site.

Fig. 2 is a block diagram depicting the flow of video, audio, and data transmission between the central station and the remote patient site according to one embodiment of the present invention.

Fig. 3 illustrates the specific flow of signals to and from a particular patient site.

Fig. 4 shows a flow chart illustrating a typical flow of steps in enrolling a new patient in the health care system according to the present invention.

Fig. 5 shows a sample computer screen reflecting a typical computer-driven initial patient assessment according to the present invention.

Fig. 6 is a sample of a clinical protocol according to the present invention.

Fig. 7 is a sample of a patient interaction screen illustrating entries of patient data against established parameters for that patient.

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Fig. 8 shows a flow chart illustrating the treatment of a single patient using the system of the present invention as well as the interaction of the steps.

Fig. 9 provides a representative example of one page of a care plan.

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DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENT

Reference is now made to the figures wherein like parts are referred to by like numerals throughout. With particular reference to Figure 1, the basic equipment used for the interactive communication of the present invention is indicated generally at 10. The central location or central station 11 includes a computer 12 of sufficient speed and memory capacity to adequately handle data retrieval, manipulation, storage, and graphical display of retrieved patient information, patient history, protocols, and education software. Alternatively, such computer 12 may be linked to another device which is capable of providing these functions. The computer 12 or linked device will be equipped with patient management software or a database to facilitate patient visits, patient assessment, data management and presentation, education, and the inter-relationship of the various segments of the health care system. A camera 13 and audio component 14 such as a microphone are mounted in such a fashion as to be capable of receiving an image and the voice of the health care practitioner for transmission to the patient. A modem or other device capable of data transmission 15 is provided as well as a video display device such as a monitor 16 for display of data as well as display of the video image of the patient transmitted to the central station 11 from the remote patient site 17. The video display and audio components should be of sufficient quality to ensure a clear presentation of the patient to the health care professional.

The remote patient's site 17 includes a television monitor or other video and audio receiver 18 for life-like display of the image and sound of the health care professional to the patient. A camera 19 and microphone 20 are fixed in a location to achieve a desired view and clear sound of the patient for transmission to the central location during the electronic home visit. Ideally, this camera 19 is equipped with features such as pan, zoom, and tilt which may be controlled remotely from the central station 11 to assist the health care professional in observing and monitoring certain physical conditions. A data transmission device 21 such as a modem may also be desired at the remote patient site. Such a device may be used for delivery of data to the central location 11 and may also be used via an activation device 22 to initiate a call to the central location 11 or another location such as an emergency care facility.

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In the preferred embodiment, the monitor **18** is modified to make it capable of remote delayed turn-on and automatic turn-off. More specifically, the monitor **18** is equipped with a signal sensing device capable of detecting a transmitted signal in the form of a video signal, audio signal or any other perceptible activation signal; a patient warning device capable of producing an alerting signal such as a beep or tone; and a timer mechanism. When an activation signal is sent from the central station **11** to a particular remote patient site **17**, the activation signal is detected by the signal sensing device in the monitor **18**. Upon detection of such a signal, the patient warning signal and the timer mechanism are activated. The timer then begins a countdown of two minutes or whatever preselected interval has been set. Upon activation of the warning device, a beep or other warning will sound for a brief period to alert the patient that there is an electronic call being initiated from the central station **11**. If desired, additional warnings may be sounded at preselected times later in the timer countdown. At a prescribed interval, the timer will complete its countdown and the monitor **18** and the camera **19** will be activated.

Other desirable features at the patient site may include a medical monitoring device (not shown) which is economical, simple in construction and use, and which is capable of sensing, detecting, and/or monitoring certain physiological measurements. A typical device would consist of a micro-computer base unit capable of gathering data from proprietary non-invasive digital medical diagnostic equipment such as blood pressure equipment, thermometers, electronic stethoscopes, peak flow meters, blood glucose monitors, blood coagulation monitors, blood cholesterol monitors, pulse oximeter, weight scales, uterine activity monitors, electrocardiogram, non-invasive blood pressure, and infusion equipment. Ideally, the device would comprise wired slots mounted in a rack frame. One such slot is used to connect to a modem or other such communication device. The remaining slots are available for connection to desired medical monitoring equipment as appropriate for a particular patient's needs. Each such slot is universal allowing any monitoring function to take place in a given slot. Software provides the necessary identity of the function. Through this modularity approach, a patient is able to purchase or lease only those monitoring devices relevant to his or her particular needs.

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Such a medical monitoring device further has the capacity to either immediately transmit the collected data via a modem to the central station 11 or store it for future transmission. For instance, the homebound patient may take multiple readings at prescribed intervals. Each reading would be time coded and stored automatically for transmission during the nurses video visit or until a predetermined transmission time. Privacy of patient data is protected via software limiting downloading of patient data via telephone number and pass coding.

An additional feature in making any such system economical is that it be able to incorporate a wide variety of instrumentation and integrate that instrumentation into the operation of the unit. This is an important factor, as the ability to incorporate such "off-the-shelf" instrumentation substantially reduces the cost to the consumer of the interactive video medical monitoring system. In addition to accepting "off-the-shelf" medical monitoring devices, the ports of the medical monitoring unit of the present invention may be programmed to interchangeably accept a variety of "off-the-shelf" instrumentation. This allows for greater ease of system operation as a variety of instrumentation models may be selected which, for one reason or another, may be more appealing or necessary to a particular patient.

For example, while it may be the usual case to take a patient's temperature reading from the ear canal, in patients for whom the ear canal is covered or blocked or painful, it may be more useful to substitute an oral thermometer. Another desirable substitution may be in the use of a finger- or wrist-type pulse and blood pressure unit versus the arm-cuff type blood pressure unit. This selection would depend on which type of device is more convenient for the particular patient to manipulate. It will be clear from this description that the ability to substitute instrumentation and the ability to quickly and rapidly adapt any available medical instrumentation to use in the home patient monitoring system is a significant and beneficial feature of the Automated Patient Monitoring Device (APMD).

In general, the APMD provides data collection, data storage and data transfer in conjunction with home patient monitoring systems. The APMD first functions to allow the interconnection of any "off-the-shelf" monitoring device with the unit and to then acquire patient data through the monitoring device which is a patient-operated medical instrument. The APMD then stores the acquired data for downloading of the data to the central patient monitoring site. Alternatively, the APMD can be operated in real time to acquire data from

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the patient-operated medical instruments and to immediately transmit the acquired data to the central site.

One embodiment of the APMD is provided with five ports for accepting patient-operated medical instruments. The instrument connection ports in this embodiment are multiple RS-232 serial data ports, a bi-directional infrared data port (IRDA) and a port for interfacing with a radio frequency reception and transmission device. This variety of available ports serves to provide the necessary mechanical connection needed for a wide range of medical instrumentation. Once the mechanical connection is provided, however, it is necessary to ensure that the data type and format provided by the "off-the-shelf" medical instrument being connected with the APMD is of a data type and format which corresponds to the system transmission device and read-out instrumentation at the central site.

In order to accomplish this conformation of the "off-the-shelf" medical instrument data type and format, the APMD is provided with a programmable central processor which is accessed by a laptop computer by a care giver who is installing the "off-the-shelf" medical instrumentation. Through the use of the laptop computer, the APMD central processor is programmed to read the raw data as transmitted from the "off-the-shelf" medical instrumentation and to reconfigure the raw data into a type and form which is compatible with the home patient monitoring system and central site. After this conversion it also may be convenient or desirable for the received and converted data to be stored for future transmission to the central site.

Specifically, the APMD is provided with a 16-bit embedded microprocessor having 128k of non-volatile memory (NOVRAM), 128k of program memory (UVPRAM), and 128k of static RAM. It is the program memory (UVPRAM) which is accessed and programmed by the care giver with a laptop computer (or other program source) in order to program the APMD to properly receive and format the raw data from the "off-the-shelf" medical instrumentation for later transmission. The programming of the memory will vary from instrument to instrument depending upon the parameters of construction of the particular instrument. However, the care giver will have advance notice of the particular type of instrumentation to be used with a particular patient. This advance notice is received during the analysis of each patient's medical needs. This advance notice provides sufficient lead time to allow the particular programming requirements of any unusual instrumentation that may need to be

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developed. In addition, it will be appreciated by those skilled in the art, that the ability to program and reprogram the APMD central processor permits the APMD unit to be continually and immediately adjusted to accept the newest developments in medical instrumentation as the instrumentation comes on line. In this manner, the patient's needs can be served immediately and the APMD can be adapted to meet the changing needs of both the patient and the offering of the medical technology instrumentation market.

In operation, a care giver selects a particular medical instrument which is appropriate to the specific needs of a patient. The medical instrument is then attached to one of the RS-232 ports or the infrared port or radio frequency port of the APMD device and the laptop computer is then attached to the APMD via a set-up port. The programming of the memory of the microprocessor is then effected to allow the APMD to properly recognize and reformat the data received from the now connected "off-the-shelf" medical instrument.

Once the care giver has completed the program memory setup via the laptop computer, the instrument is interconnected with the memory of the APMD via a serial port RJ-12 jack. Upon initiation of the connection, the APMD microprocessor will determine whether the data format transmitted by the medical instrument matches the expected format which has been programmed into the memory by the laptop computer and care giver. Should the data transmitted by the instrument not match the programmed format, an alert or error message will be presented to the care giver. This alert will be both audible and visual taking the form of a sound file and flashing light-emitted diode or LED.

Once the medical instrument is properly connected to the APMD and in operation, patient data will be acquired by the instrument and transmitted via the cable to the memory of the APMD where the necessary reformatting of the data can occur. The data is then transmitted to the central site for evaluation. Alternatively, the data received can be stored in the non-volatile memory (NOVRAM) in conjunction with a time of day and date and identity of the instrument from which the data was received. Storage of the data in this fashion is used when it is desired to take a number of patient data points through the course of a day or week and to then transfer that information in batch form to the central site for evaluation and discussion with the patient. This ability to collect and store the patient data prior to transmission, minimizes patient inconvenience and minimizes the sense that the patient is "attached" to the instrumentation and provides the patient with a sense of independence and

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control over the monitoring of their health situation. In addition, the ability to retrieve and store data prior to transmission and to then offer batch transmission of data to the central site permits a substantial reduction in monitoring costs as the central site medical team interaction with the patient can be reduced to a single period in a time interval when all the data has been collected and is ready for analysis.

In order to transfer information conveniently, the APMD is provided with an automatic answer mode which allows the central site to contact the APMD via modem from the base station and to then download any data which has been collected since the last contact between the APMD and the central site. The APMD also is provided with an "originate" mode which allows the APMD to initiate contact with the central site via modem. This contact can be initiated at either a preset time or in response to a pre-programmed medical event or condition.

Examples of such conditions could be that the amount of data stored in the NOVRAM is near the storage capacity of the NOVRAM and it is necessary to transmit the data to the central site in order to permit additional collection of data. Another such condition may be that the data being collected by the instrumentation is, for one reason or another, out of proper data ranges. In this case the APMD could contact the central site for data evaluation in order to determine whether there is a medical event occurring with the patient or whether the data being received from the medical instrumentation is in error for some reason. Yet another condition which could initiate the APMD contacting the central site is a pre-programmed medical event. Such an event could take the form of high or low blood pressure readings which are outside of a pre-programmed range established by the care giver through the laptop computer in the APMD central memory. Another such event could be in the case of a patient with diabetes, an indication that the patient's insulin is out of range and requires attention.

In this manner, the APMD can be used as a type of emergency medical monitor which would allow critical functions of the patient health to be monitored without continuous invasion of the patient's home and privacy. This permits the APMD to be conveniently used to allow a patient such as an elderly individual to live and function at home, independently, while having their basic well being continually monitored. This monitoring avoids family members

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being concerned that the elderly individual would be caught up in a medical emergency at home without the means to provide notice that medical assistance was needed. Through the use of the APMD, the onset of any catastrophic event can be noticed by the instrumentation and the central site can be alerted by the APMD using the originate mode.

5 One embodiment of the APMD is comprised of a wall-mounted 12 volt DC power supply. RJ-12 jacks are provided for interconnection of a telephone line for communication with the central site by the APMD and for interconnection of the laptop computer in order to set data format and connection requirements. Serial communications between the various components of the APMD are through four dual UARTs (define this term) operating at 9600
10 baud. Five of the UARTs devoted to the interconnection of the external medical instrumentation through RJ-12 modular connectors. Another of the UARTs is dedicated to the bi-directional infrared port and another is devoted to the radio frequency interface. The last of the UARTs is dedicated to the reprogramming of the APMD with the laptop. The modem used in one embodiment is a variation of a Rockwell® "socket modem" which can be
15 removed and upgraded as needed. One embodiment of the APMD operates at the current standard of 33.6k voice-over data with standard Hayes modem command sets being used.

Referring now to Figure 2, depicting one embodiment of a communication link
20 between a central station 11 and a remote patient site 17 according to the present invention. Audio, video, and data information is carried over a public or private transmission medium of coaxial cable, twisted pair copper, microwave, POTS, fiber optic cable, or infrared laser, ADSL, HDSL, or other transmission medium now known or not yet implemented; such transmission medium indicated generally at 23. The particular transmission medium chosen
25 in any particular instance will depend on factors such as the availability and costs of the various options in a given area.

In a presently preferred embodiment, coaxial cable or fiber optic is used as the transmission medium for the audio and video signal as it is readily available, cost effective, and offers the ability to carry the transmissions on a discrete line thereby safeguarding
30 patient privacy. In this embodiment, a video signal, which originates at the base site 28 is transmitted to a receiver 33. The signal is then fed to the video distribution amplifier 24

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where the signal is distributed to the picture-in-picture 25 and to the transmitter 26. A video signal is received from the central station 11 and combined in the picture-in-picture 25 unit. Both videos from camera 13 (central station 11) and base site 28 are displayed on monitor 16, permitting the health care professional to view the patient and themselves.

5 The video signal from camera 13, which has been fed via the distribution amplifier 24 to the transmitter 26, is then united with an audio signal from microphone 14 which has been picked up at the microphone 14 and sent via audio cable directly to transmitter 26. Both signals are then transmitted via coaxial cable or fiber optic 23 to a receiver 27 at a base site 28. This base site 28 serves as a central receiving area within a neighborhood, apartment
10 building, or other area central to a group of patients accessing the system.

From the receiver 27, the audio and video signals are fed into a multi-point switcher/router 29 of variable capacity. Substantially simultaneously with the transmission of the audio and video signals, a data signal originating at the central station 11 is sent via a communication device 15 over a telephone network to a communication device 30 located
15 at the base site 28. This data signal is encoded with an address identifying the particular patient address being accessed. At the switch/router 29, the audio, video, and data signals are directed to each individual patient site, such as the site marked 17. Thus, as a signal comes in from the central station 11, the switch/router 29 is utilized to identify the particular patient address encoded in the signal and then switch the transmission from the base site 28
20 to that particular patient site 17. Figure 3 illustrates the specific flow of signals to and from a particular patient site.

Alternatively, when audio, visual, and data signals are received at the base site 28 from an individual patient site 17, the switch/router 29 will direct the signals either to the central station 11 or to another remote patient site 31 within that switching network. Where
25 the signals are switched and routed to the central station 11, the audio/video signals flow to a transmitter 32 where they are transmitted via coaxial cable or fiber optic to receiver 33, to the picture-in-picture 25 and displayed on monitor 16. By first receiving the signals from the central station 11 or a remote patient site at a central base site 28 location equipped with a receiver and transmitter, it is not necessary to place an expensive modulator at each remote

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patient site 17. Any data signal originating from a remote patient site 17 is transmitted by telephone network from communication device 30 to communication device 15.

In addition to address identification, the switch/router 29 at the base site 28 also permits one-way broadcast format from the central station 11 in real time to all of the patients at a particular switching site simultaneously. Such broadcast means may be very effective in providing on-going education or updates of information.

If the chosen transmission medium 23 is other than a publicly-switched network of coaxial cable, the central station and remote patient information may be transmitted simultaneously by means of dedicated coaxial or fiber optic cable. In the case of fiber optic cable, non-compressed audio, video, and data information is transmitted via an analog or digital transmitter directly onto a fiber optic cable on a specific frequency and received at either the central station 11 or the remote patient site 17. Radio frequency (RF) equipment is employed for data transmission coincident with video and audio. In each such case, a discrete transmission line exists in both directions maintaining privacy of all such transmissions. In the case of a publicly-switched network, such as that discussed above as a preferred embodiment, audio, video, and data transmissions between the central station 11 and the patient site 17 are placed on a specific frequency and transmitted directly, or via a controlled switching/routing station, between the two points. Signals are not available to any other site on the network. Privacy and control is maintained by the switch/router 29 and may include additional signal scrambling devices (not depicted).

The database located at the central station 11 further provides for security and confidentiality. Each patient's name and picture, as well as the patient's assigned patient identification number, is listed in the database to provide verification upon connection that the proper patient is being seen by the health professional. Therefore, when a particular patient is called up either by name or patient identification number at the central station 11, a picture of that patient will be displayed on the screen to the health care professional allowing for easy and certain identification once the connection is made with the patient. To further provide system integrity, the database is password protected. All nurses or other health professionals must use a password and an assigned user ID to access patient records or conduct an electronic home visit with a given patient. Use of the password and user ID

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upon sign-on to the system will serve as a digital "signature." Once a patient visit on the system is complete and the nurse or other professional has signed off, the patient information cannot be altered, assuring the integrity of the patient file and accountability and responsibility for the actions taken. One supervisor is selected per central station site. Only
5 this person is allowed access to secured areas of the software.

Referring now to Figure 4, entrance of a patient into the comprehensive health care system of the present invention begins with an initial assessment of a potential patient, depicted generally at 33. This in-person initial assessment serves to collect initial information about the patient which is later entered into the database to become a basis for
10 the patient's disease management, education, and plan of care. This initial meeting will also serve to personalize the interaction, answer patient and family questions about the system, and identify other important data such as referring physicians. Based on this initial data, it will be determined whether or not the remote system of health care is appropriate for a particular patient at that time 34.

Upon acceptance of a patient into the system, equipment needs are evaluated, the patient is given pertinent information, certain forms are completed for the patient file, and an in-depth assessment meeting is scheduled 35. The next step is an approximately two-hour meeting with the patient to complete a detailed assessment form 36. Such an assessment
15 may be computer driven to accumulate information such as that depicted in the representative computer screen as illustrated in Figure 5. The required equipment such as a television, microphone, cabling, and medically monitoring devices are then installed and the patient is carefully trained on their use and on what to expect during a typical electronic home visit 37 (Fig. 4). The detailed information gleaned from the in-depth patient assessments are entered
20 into the computer database at the central station 11 and the electronic patient file is established 38.

An initial rapport-building visit may take place at this time, but, prior to the first on-line patient clinical visit, the nurse or other health care professional generates suggested doctor's orders 39. These suggested doctor's orders are developed from the appropriately approved clinical protocols based on that patient's medical history and the patient information
30 developed during the patient assessment. Within the home health care system of the present

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invention, protocols are established for treatment, assessment, and evaluation of patients based on various physical and psychological disease criteria. The protocols are part of the system database and are readily accessible to the health care professional as patients' needs arise. Figure 6 provides a sample of a typical protocol according to the present invention.

5 Once suggested doctor's orders 39 are developed, they are presented to the patient's physician for additions, edits, and approval. Once the doctor's orders are signed (Fig. 4, 39), they are entered into the patient's clinical record in the software and patient on-line clinical visits may begin. In addition to patient histories and doctor's orders 39, parameters of acceptable ranges for each patient's vital signs (blood pressure, pulse, temperature, blood
10 sugar, weight, height, lab values) as established by the patient's physician are entered into the software to further serve in the proper assessment and evaluation of the patient. As an on-line visit occurs with a given patient, vitals, weights and other such information is either automatically transferred to the central station or is manually entered by the nurse professional logged into that record and conducting that patient visit. The date and time of
15 such readings and entries is also automatically indicated at that time providing a thorough and accurate record. An example of entries of such patient data within an active on-line patient interaction screen is illustrated in Figure 7. When a patient's vital sign or other such reading falls outside of the acceptable range based on the set parameters entered into the electronic patient file in the database, a warning alert may be activated either visually,
20 audibly, or both at the central station 11.

In addition to providing immediate access to medical and personal information relevant to a particular patient during the on-line visit, the database either directly, or by link to another resource, provides access to educational modules which are relevant to that particular patient's needs. These patient education modules may be stored on CD ROM, cassette,
25 diskette, videotape, hard drive, or any other storage medium. In a preferred embodiment, these educational segments are confined to a minimal time period such as three to five minutes. It has been discovered that providing patient information in frequent, yet brief, segments is more effective in achieving the educational goal. Other patient education and disease management skill training aids may include on-line slide shows, equipment
30 demonstration, illustrations, photographs, and live expert health care professional presentations. Where a group of patient users are grouped through a switch/router at a base

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station, the education tapes relating to general matters or professional presentations may be presented in broadcast format to the entire group or all of those who are interested.

Most importantly, the database is designed such that information in a patient file, as well as events which occur spontaneously during an on-line visit, may automatically trigger the presentation of educational materials via the in-place communication system to the patient. For example, if a patient's vital readings indicate a problem with high blood pressure, the database can be programmed to recognize this problem and initiate the selection and presentation of educational segments on control of blood pressure to that patient. It will be appreciated that a health professional may also manually select educational materials for the patient depending on feedback from the patient during the on-line visit.

Through planned interaction of the patient assessment program, the set parameters, the established protocols, the education components, and the trained personnel, the home health care system of the present invention provides a comprehensive medical program for each individual patient. Figure 8 shows an overview of the home health care system of the present invention by following a patient through the system. As previously indicated, as a patient enters the health care system, a thorough assessment is made and detailed information regarding the patient is collected. This initial personal contact also serves to familiarize and personalize the system and its personnel to the patient. The collected data is then entered into the database at the central station and becomes the patient's electronic file. At that time, an assessment is made of that patient's needs, which triggers the development of a care plan. (Fig. 9 provides a representative example of one page of such a care plan. These care plans are approved core plans based on specific indications of the patient.)

The patient's physician then reviews the patient's information and the core care plan and provides initial physician orders, revising the care plan as appropriate for that patient, identifying acceptable parameters for vitals and other measurements, and providing other medical directives such as medication orders. The initial physician orders, the patient data from the initial assessment, libraries containing information and educational support materials, and relevant approved clinical protocols are all linked within the database so as to support the nurse or other health care professional in making decisions as to how to conduct the interactive home visits with a particular patient. The nurse, assisted by the

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database program, assimilates all of this information and these resources and creates a computer-driven "To Do" list which will serve as a guide for the electronic visit including items such as questions to ask, observations to make, vitals to check, and medications to dispense.

Patient visits are set up for predetermined intervals such as daily, twice daily, or even more frequently. A contact is initiated by the health care professional entering their password and user ID into the computer at the central station and then accessing a particular patient's records. The data signal travels along the transmission line to a switch/router at a base location near the remote patient site where the electronic address for that patient is recognized and the transmission is directed to that patient's home monitor. The video sensor in the monitor senses the video signal, starts the timer countdown, and sounds an alert to remind the patient that a visit is about to commence. Such an alert will allow the patient to take care of privacy concerns and ready themselves before the monitor and camera activate. If desired, additional warning signals may sound at specified intervals up to the point where the audio/video equipment is automatically activated and the visit begins.

When the health care professional contacts the patient via the interactive televideo system, they will perform the tasks on the "To Do" list with electronic "check-off" as each task is completed. Where available, a medical monitoring device in the patient's home will automatically send digital information as to certain vital signs as ordered by the physician. Such tasks can also be performed manually by the patient with the direction of the health care professional. As the patient and the professional interact, there is an opportunity to respond to immediate concerns or developing problems. Where the health care professional believes that education of the patient or the family would be helpful, the system is linked to supply appropriate education modules which can be sent to the patient at that time or at a later agreed upon time. In addition, the database may be programmed to automatically direct such education materials to the patient via the communication link upon the recognition of certain criteria if that is desired.

The computer-assisted visit will document activity, information, prescribed education, medication taken, and changes in condition. In addition, the system allows for the nurse to comment with additional notes or observations. Where a pre-set parameter is exceeded, that parameter will highlight in red or in some other appropriate fashion which will alert the professional and the database program may also make automatic notation of the exceeded

-23-

parameter. The database may also be programmed to alert the health professional of other changes in a patient's condition. When the database signals a nurse or the professional observes a change in the patient's disease process, a change of condition form is prompted on the screen at the central station which will document the need for intervention. The system will also permit the nurse to record a portion of the patient's visit to disk or videotape if it is believed that such a pictorial record will assist in further evaluation of the patient's problem.

At the end of the visit, reports such as Physician Reports, Activity Logs, or Change of Condition Reports will be either automatically triggered or a professional can initiate production of certain reports. Where a patient's condition warrants, the database may automatically trigger a report to the physician seeking re-evaluation of the patient or possible intervention. Where there are no immediate triggering events, a physician report will be triggered on some pre-set interval, such as every sixty days, to ensure continued physician follow-up and review. These physician reports will contain a digital data summary of all of the patient information and may even include a video clip of the patient where such is useful. At the automatic sixty-day physician evaluation or at an earlier time where circumstances warrant, the physician may issue new orders which will then be entered into the patient database and trigger a new "To Do" list.

Beyond the specific patient contact, the health care system of the present invention provides system-wide assessment and education. Central stations may be networked to allow on-line training sessions for health care professionals. On-line, on-site, and computer training modules, as well as a training manual, are furnished on areas such as:

- Orientation
- Home Health Policies & Protocols
- Patient Enrollment
- Case Management
- Patient Assessment Interviews
- Documentation
- Patient Education/Disease Manag.
- Televideo Nursing Techniques
- Patients with Special Needs
- Emergency Management
- Adult Education Techniques
- Non Emergency Management
- Management of Non-Compliant Patients
- Quality Assurance and Improvement
- Patient Discharge Protocol
- Prof. Coordination & Consultation
- Computer Use/ Equip. Troubleshooting

A specialized training program for the professionals involved in the system leads to consistent and quality care throughout the system and ensures that when one professional must fill in for another, the patient will not be traumatized by the change.

5 System-wide assessment also ensures quality medical care to each patient. With a defined method of record keeping and report generation, it is possible to compare and contrast the records and results of several health care systems operating according to the current invention to achieve an improved method of care for each of the systems and, thus, for each of the patients. On some regular basis, a central management may gather and
10 analyze data from all databases in the central system to a central database. Insight gained from this analysis may then be shared with individual system users to improve the database and methods of treatment within all systems and thus lead to continually improved quality of care. For example, if a nurse in one location is able to care for a patient with COPD in 15
15 minutes a day with satisfactory patient outcomes, while other nurses routinely need 25 minutes, analysis of the difference will be triggered leading to increased efficiency and quality of care by the sharing of the more effective procedures with all other nurses. Similarly, where there is an undesirable result with the current procedures, the situation will be identified and corrected to the benefit of all other patients. This system of checks and balances also serves a purpose in risk and liability management. For instance, where potential risks of omission
20 are identified, they can be established as automatic "triggers" in the case management software to assure that televideo nurses are reminded and such omissions can be avoided.

 It should be appreciated that the comprehensive home health care system of the present invention is capable of being incorporated in the form of a variety of embodiments, only a few of which have been illustrated and described above. The invention may be
25 embodied in other forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive and the scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

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I CLAIM:

1. A system for providing comprehensive medical, social, physical, or psychological care and support to a person located at a remote location via interactive video and audio transmissions between said person and a care provider located at a central station, said system comprising:

a database including information regarding the personal, medical, social, or psychological history or condition of said person;

means for assessing said person's current condition during said transmissions and updating said person's personal, medical, social, or psychological information based on that assessment;

said database further including or having access to educational materials;

means for identifying educational materials relevant to said person's personal, medical, social, or psychological information, history, or condition; and

Means for delivering said educational materials to said person via said interactive transmission.

2. A system for providing comprehensive health care to a patient at a remote location via interactive video, audio, or data transmission between said patient and a health care professional at a central location, said system comprising:

means for collecting and storing personal and medical information of said patient in a database for use in said health care system;

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means for establishing an electronic patient file in said database, said electronic patient file including said personal and medical information, said electronic patient file further including or having access to physician's or other trained professional's orders, reviews, or directives for the care, support, or assessment of said patient;

means for storing educational materials for use in said health care system, said materials being stored so as to be electronically accessible to said database;

means for establishing medically-approved protocols for treatment, assessment, and evaluation of said patient, said protocols being entered into or accessible to said database and said patient's electronic file;

means for establishing medically-approved parameters for acceptable ranges for said patient's biological data, said parameters being entered into or accessible to said database and said patient's electronic file;

means for establishing an electronic "to do" list or guide for care of said patient, said means including the linkage of information in said database, said patient's electronic patient file, the protocols relevant to said patient, and said patient's parameters;

means for conducting an interactive electronic home visit between said patient at said remote location and said health care professional, said means including first audio-visual means for generating a first audio-visual signal of said health care professional at said central location;

first transmission means for transmitting said first audio-visual signal to said patient at the remote location;

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first display means for receiving and displaying said first audio-visual signal to said patient at said remote location;

5

second audio-visual means for generating a second audio-visual signal of said patient at the remote location;

second transmission means for transmitting said second audio-visual signal to said health care professional at said central location;

10

second display means for receiving and displaying said second audio-visual signal at the central location;

first data means for generating a first data signal from information collected at said remote location;

15

first data transmission means for transmitting said first data signal from remote location to central location;

first data display means for receiving, storing, or displaying said first data signal at said central location;

20

second data means for generating a second data signal at central location;

25

second data transmission means for transmitting said second data signal from said central location to said remote location;

second data display means for receiving, storing, or displaying said first data signal at said remote location;

30

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whereby said health care professional and said patient are capable of substantially simultaneous interactive communication,

5 said health care professional using said "to do" list, said protocols, and said parameters to assist said health care professional in conducting said electronic visit and in the care and on-going assessment of said patient, said health care professional further assessing the patient based on said visual, audio, and data transmissions from said patient to said central station;

10 whereby said "to do" list, said database, and said electronic patient file is updated based on said assessment and relevant education materials are identified based on said assessment and displayed to said patient via said interactive transmission.

- 15 3. The health care system of Claim 2 wherein the assessments of all patients in the system and the care provided to said patients are correlated to evaluate and improve the effectiveness of the system.
- 20 4. The health care system of Claim 2 wherein specific education materials are automatically identified and sent electronically to said patient based on information recorded in said electronic patient file.
- 25 5. The health care system of Claim 2 wherein means are provided at said remote location for collecting biological data from said patient, said biological data being transmitted to said central location via said first data communication means.
- 30 6. The health care system of Claim 5 wherein said biological data is first stored at said remote location for later transmission to central location via said first data communication means.

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7. The health care system of Claim 5 wherein a warning signal is activated in said database when said patient's biological data falls outside of said parameters.

5 8. The health care system of Claim 2 wherein each health care professional entitled to access patient files within said health care system is identified by a number or other such identification symbol, each patient enrolled in said health care system is identified by a number or other such patient identification symbol, and access to said patient's electronic file requiring entry of said health care professional's identification symbol, a password chosen by said health care professional, and said patient's
10 identification symbol.

9. The health care system of Claim 8 wherein each patient's electronic file further contains a photographic representation of said patient; said photographic representation appearing on said second display means upon access of said patient's
15 electronic file and capable of being compared with image of said patient from said second audio-visual signal upon initiation of said electronic visit.

10. The health care system of Claim 2 wherein said first display means comprises:

20 means for detecting a transmitted signal in the form of a video, audio or any other perceptible activation signal;
means for delayed remote turn on;
a timing device;
a warning device capable of producing an alerting signal

25 whereby upon detection of said activation signal by said detecting means, said timing device is activated and begins a countdown and said warning device is activated producing said alerting signal; at the end of said countdown, said first display means is turned on automatically by said means for delayed remote turn on thereby alerting said patient that an electronic visit is being initiated from said central location.

30

FIGURE 1

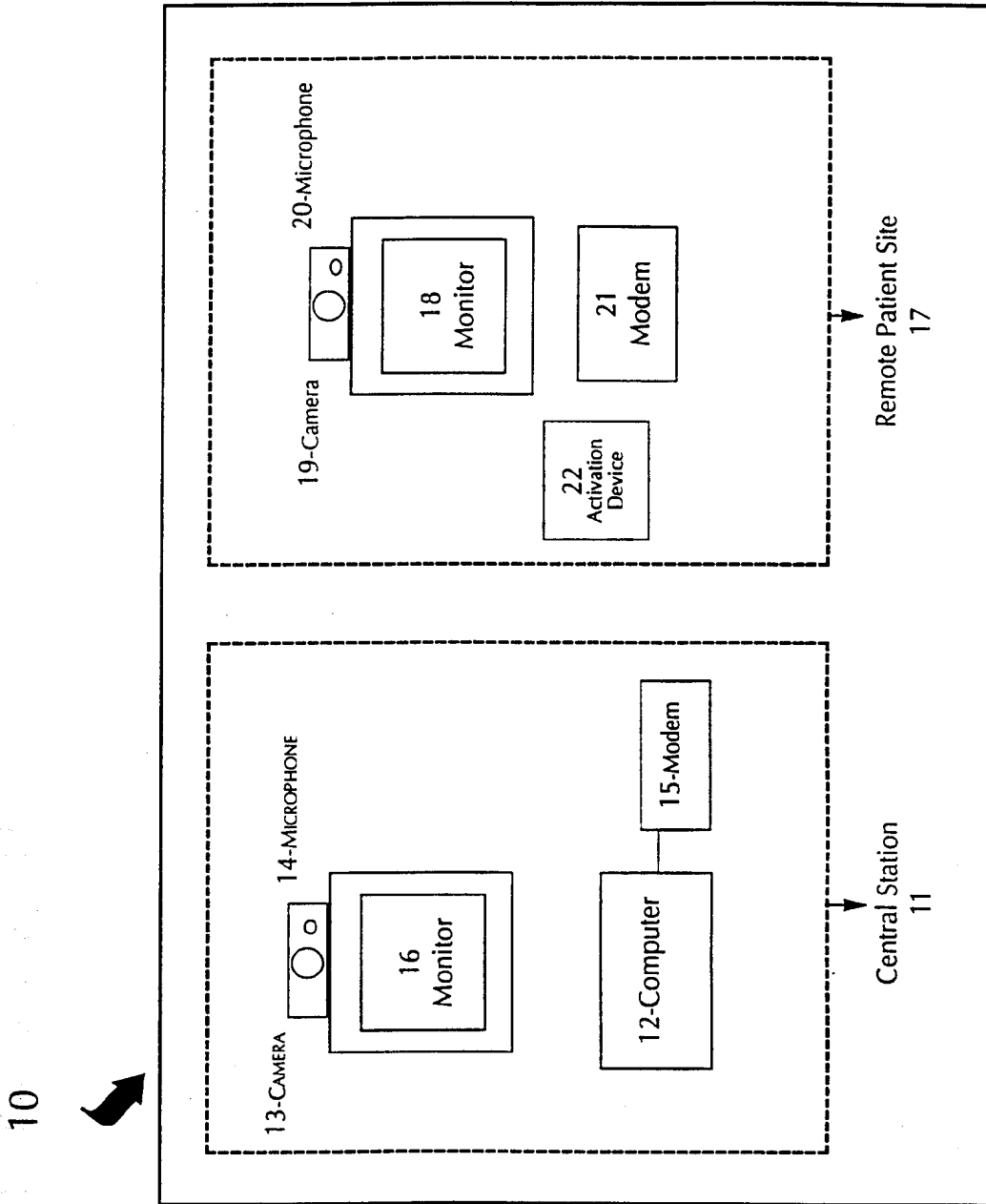


FIGURE 2

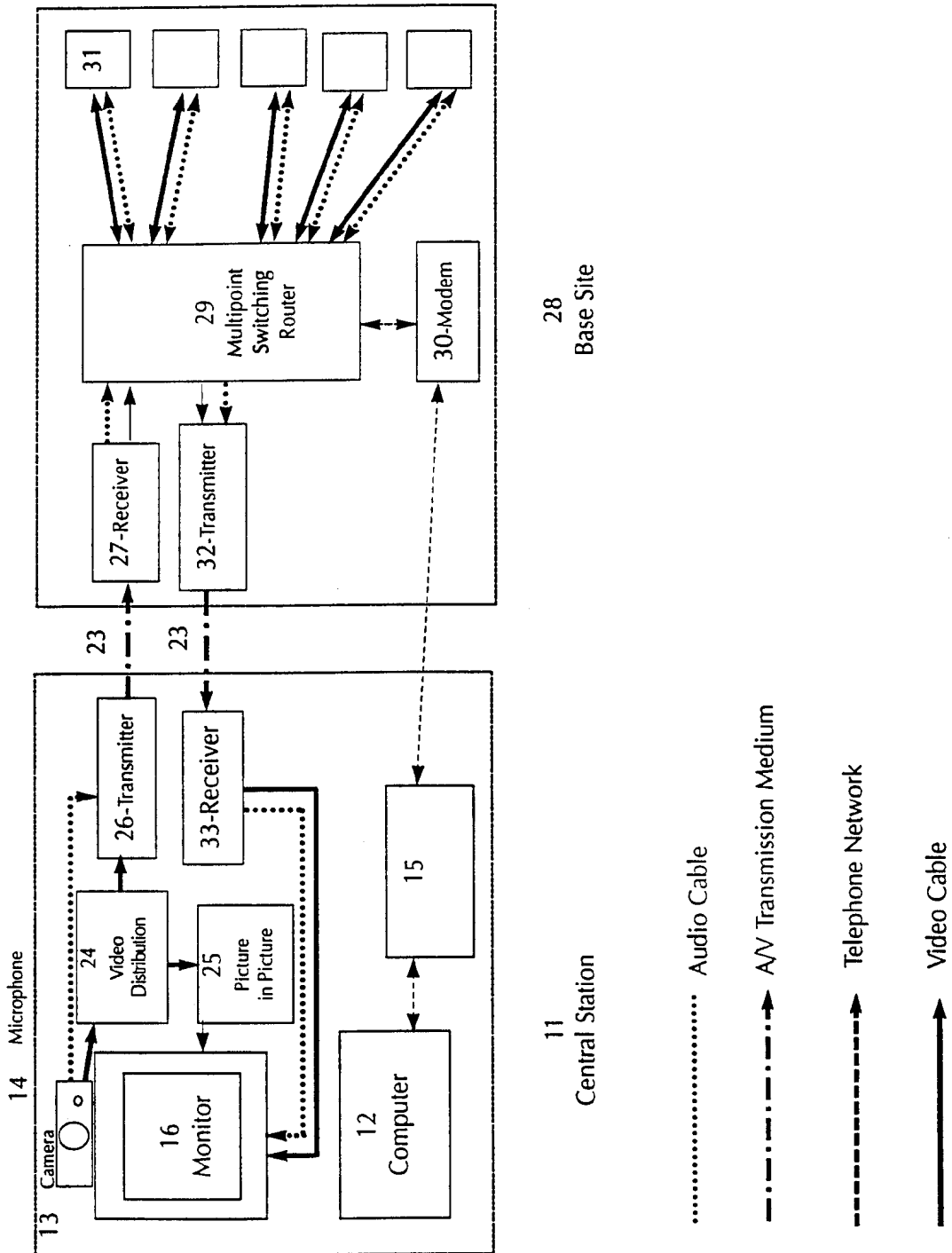


FIGURE 3

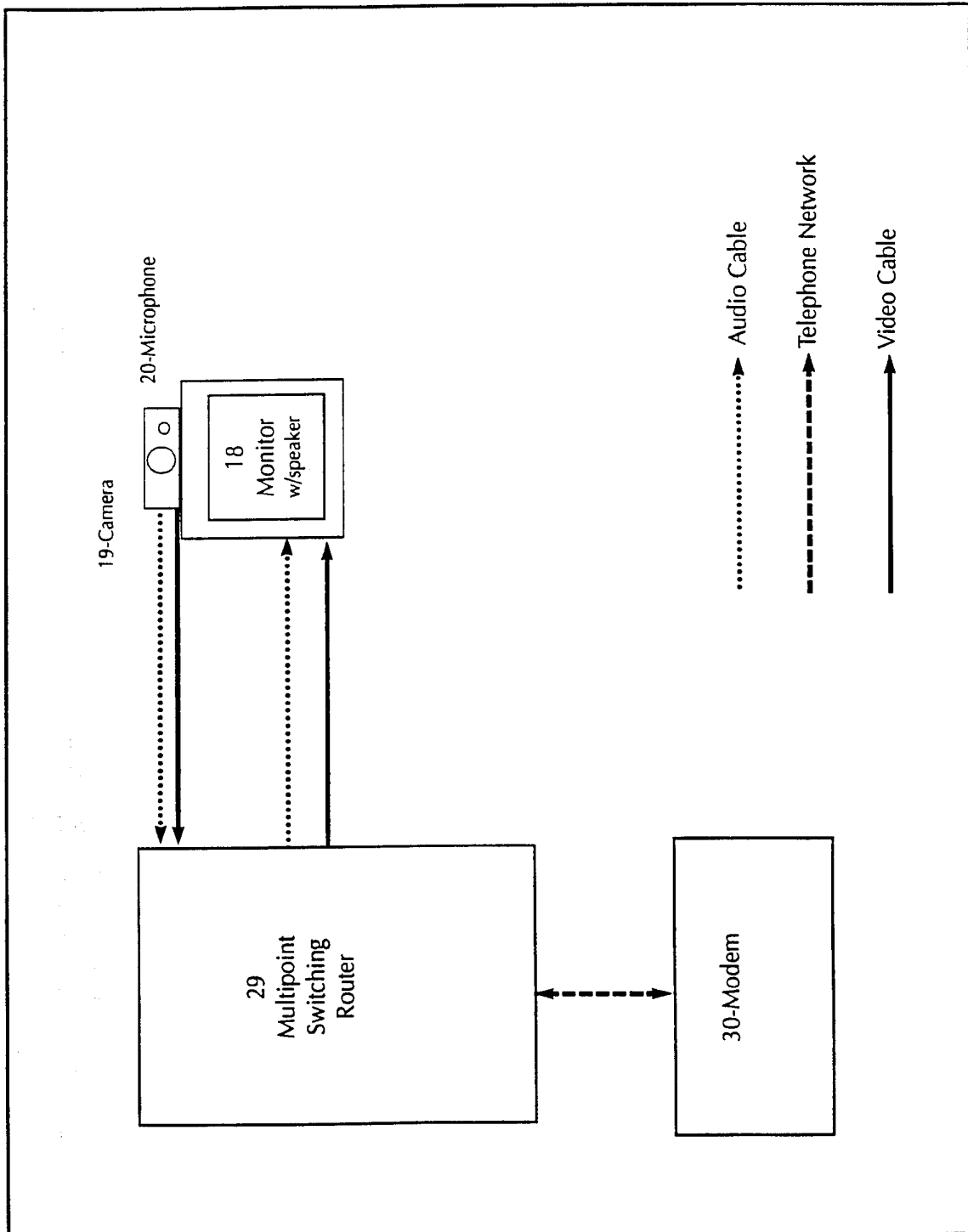
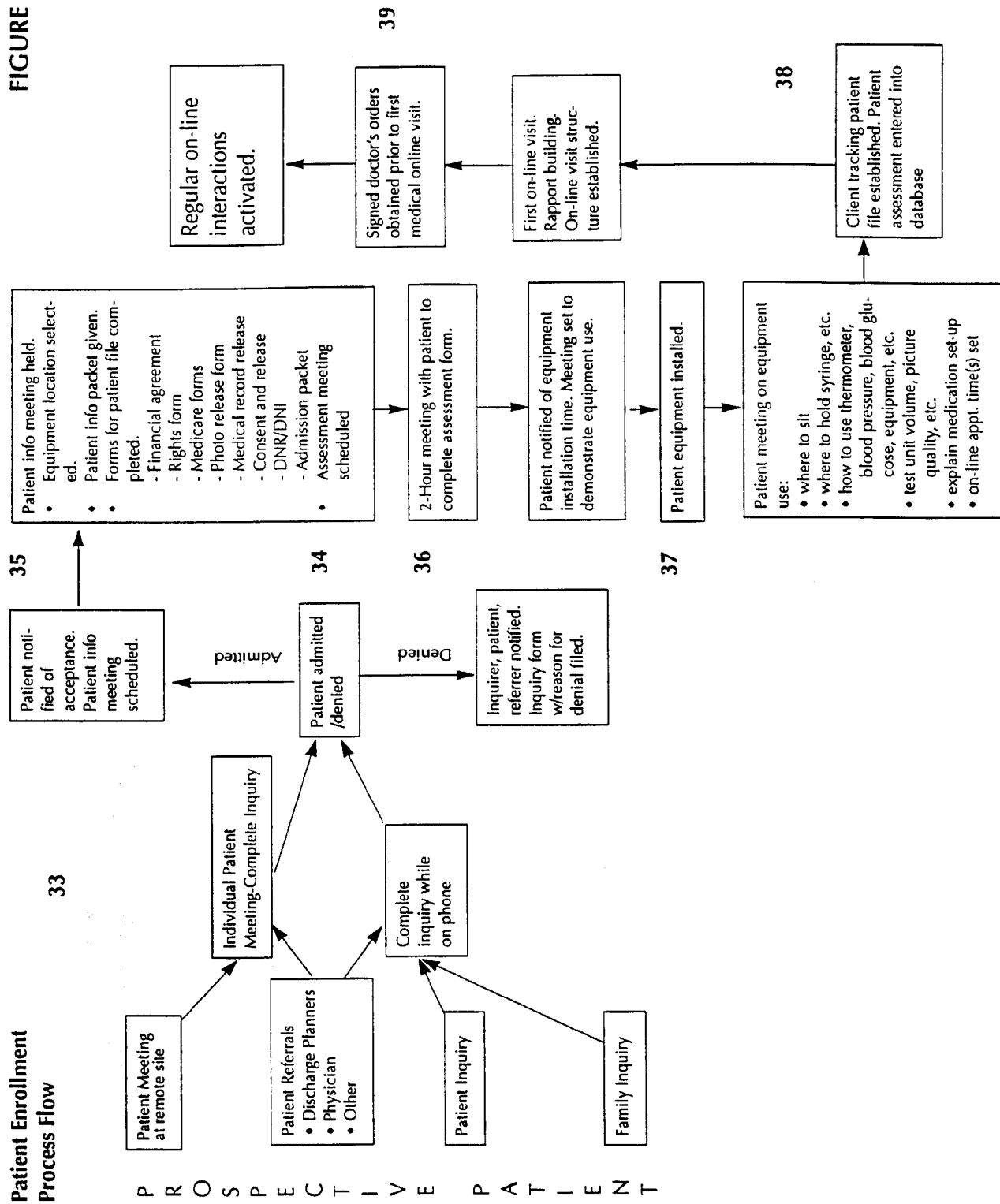


FIGURE 4



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FIGURE 5

☐ = Code the appropriate response ☐ = Check if response is applicable

| SECTION A: IDENTIFICATION | | SECTION C: FAMILY PROFILE | |
|--|-----------------------------------|---|------------------|
| 1. Date of Assessment: | | 1. Marital Status: | |
| 2. County of Residence: | | 1. Now Married | 4. Separated |
| 3. Name: | (Last) (First) (Middle Initial) | 2. Widowed | 5. Never Married |
| 4. Street, Apt. #: | | 3. Divorced | |
| City: | State: Zip: | 2. If Now Married, What Is Your Spouse's condition? | |
| 5. Phone: (With area code) | | 1. Able To Perform Routine Household Tasks Without Assistance | |
| 6. Source of Referral: | | 2. Requires Assistance With Household Tasks | |
| 1. Patient referred self | 1. | 3. Unable To Perform Routine Household Tasks | |
| 2. Family Member | 2. | | |
| 3. Friend | 3. | 3. a. Number of living children: | |
| 4. Hospital | 4. | Name | |
| 5. SRS Office | 5. | Address | |
| 6. Other (Specify) | 6. | City | State Zip |
| | | Phone | |
| 7. Payment Sources: | | Name | |
| 1. None; No Charge for Current Services | 1. | Address | |
| 2. Medicare (Traditional Fee-For-Service) | 2. | City | State Zip |
| 3. Medicare (HMO/Managed Care) | 3. | Phone | |
| 4. Medicaid (Traditional Fee-For-Service) | 4. | Name | |
| 5. Medicaid (HMO/Managed Care) | 5. | Address | |
| 6. Worker's Compensation | 6. | City | State Zip |
| 7. Title Programs (e.g. Title III, V, or XX) | 7. | Phone | |
| 8. Other Government (e.g. Champus, VA, etc.) | 8. | b. Number of deceased: | |
| 9. Private Third Party (HMO/Managed Care) | 9. | Year Of Death | |
| 10. Self Pay | 10. | Cause Of Death | |
| 11. Other | 11. | Year Of Death | |
| 12. Unknown | 12. | Cause Of Death | |
| 8. MEDICARE NUMBER (If applicable) | | SECTION D: MEDICATION HISTORY | |
| MEDICAID NUMBER (If applicable) | | 1. How many medications were taken prior to admission? | |
| SOCIAL SECURITY NUMBER | | Name | |
| 9. Interviewer's Name: | | Dose | Route |
| Title | | Time | Month/Year |
| 10. At What Location Is This Assessment Being Conducted? | | Physician(s) | |
| 1. Patient's Home | 1. | Name | |
| 2. Hospital | 2. | Dose | Route |
| 3. Other (Specify) | 3. | Time | Month/Year |
| 11. What Is Patient's Present Place Of Residence? | | Physician(s) | |
| 1. Own Residence (includes apt. or other rented housing) | 1. | Name | |
| 2. Other Private Home (home of relatives, friends, etc.) | 2. | Dose | Route |
| 3. Other (Specify) | 3. | Time | Month/Year |
| SECTION B: DEMOGRAPHIC DATA | | Physician(s) | |
| 1. Sex of Individual Screened: | | Name | |
| 1. Male 2. Female | | Dose | Route |
| 2. Birthdate: | Age: | Time | Month/Year |
| 3. Race/Ethnicity: | | Physician(s) | |
| 1. White, not of Hispanic origin | 4. Asian, Pacific Islander | Name | |
| 2. Black, African American | 5. American Indian, Eskimo, Aleut | Dose | Route |
| 3. Hispanic | 6. Other | Time | Month/Year |
| 4. Occupation: | 7. Unknown | Physician(s) | |



PAIN

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PAIN

Definition:

A sensation in which a person experiences discomfort, distress, or suffering due to irritation of or stimulation of sensory nerves, especially pain sensors. It is a complex subjective response dependent on intensity, duration, quality, impact, and personal meaning.

Signs and Symptoms:

Acute Pain:

- (Intense and of short duration)
- Lasts less than six months.
- With healing, pain ceases.
- Guarding of the painful area.
- Autonomic response (may have periods of physiologic adaption/ potential shock)
 - Diaphoresis
 - Pallor
 - Changes in vital signs
 - Changes in muscle tone
 - Dry mouth
 - Pupil dilation
- Decreased appetite
- Fatigue
- Distraction behavior (moaning, crying, pacing, seeking out other people and/or activities, restlessness)
- Self-focusing
- Shortened attention span
- Altered time perception
- Impaired thought process
- Facial mask of pain
- May or may not verbalize:
 - Pain descriptors (may deny them)
 - Fear, anxiety, anger, helplessness
 - Hope that pain will end
 - Frustration at lack of treatment
 - Increased irritability
- Occasional difficulty sleeping or awakening from sleep because of pain
- Social isolation
- Family/marital problems



PAIN

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FIGURE 6

Chronic Pain:

- Can be continuous, intermittent, and/or intense
- Does not serve as warning of tissue damage
- Increase or decrease in appetite
- Fatigue
- Preoccupation with pain
- Self-focusing
- Shortened attention span
- Altered time perception
- Impaired thought process
- May or may not verbalize:
 - Pain descriptors (may deny them)
 - Fear, anxiety, anger, helplessness, depression, hopelessness, suicidal thoughts
 - Hope that pain will end or possibility that pain may persist
 - Frustration at lack of treatment
 - Increased irritability, feeling like a burden, feelings of anger at others
- May verbalize anger at caretakers when dependent
- Disturbed sleep pattern with difficulty falling asleep: awakened from sleep because of pain
- Social isolation
- Family/marital problems
- Reduced sexual activities
- May use unproven remedies or visit quacks

Frequency of Contact:

Daily or as ordered by physician and agreed upon by the patient.

Task:

- Observation of medication usage and compliance.
- Observation of general clinical status and cognitive function.
- Implementation of self-reporting pain measurement tool (NRS, VAS).
- Observation of behaviors that indicate pain (splinting, distorted posture, impaired mobility, anxiety)
- Evaluation of intervention.

Pain

Case Management Plan

The cause of pain should always be sought, since pain is a symptom, not a disease itself. An etiology for chronic pain may not be found.

Alteration in comfort

- Complete thorough assessment of report of pain.



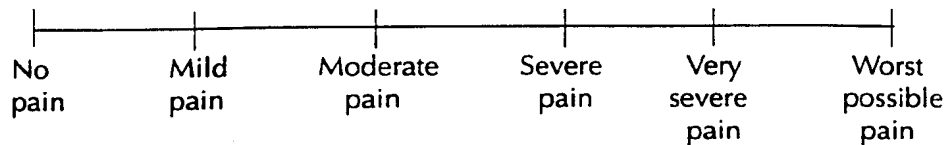
PAIN

Page 3 of 4

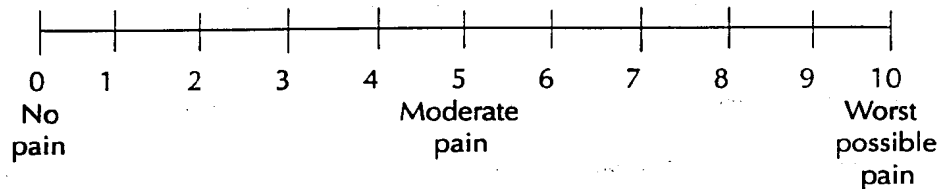
FIGURE 6

- Assess administration of medication per attending physician order.
- Adjust dosage per order. Be alert for side effects or drug interactions.
- Document effectiveness of interventions.
- Use patient's own words when documenting.
- Use numerical or visual analog scale

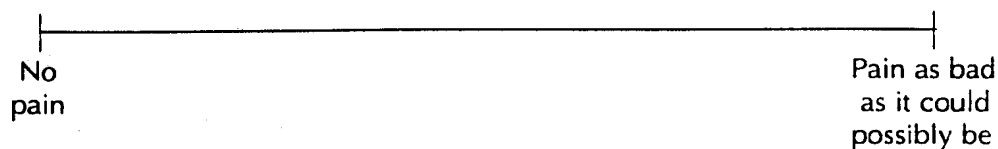
Simple Descriptive Pain Intensity Scale



0 - 10 Numeric Pain Intensity Scale



Visual Analog Scale (VAS)



- Assess vital signs, skin color and moisture, body movements (guarding, posturing).
- Teach relaxation techniques or imagery.
- Encourage positioning for comfort.
- Encourage activities for pain distraction.
- Discuss lifestyle modifications as needed.

Anxiety, depression: ineffective coping

- Evaluate coping skills.
- Encourage open communication.
- Provide emotional support and include patient's family members.
- Assess need for referrals as needed.

**PAIN**

Page 4 of 4

FIGURE 6***Activity tolerance: impaired***

- Teach patient to pace self.
- Encourage rest periods.

Nutritional deficits

- Encourage balanced diet to maintain ideal weight range.
- Assess weight for gain or loss.
- Arrange for a dietitian consult if needed.
- Instruct to report nausea or vomiting.

Interventions:

- Realization of pain as a personal perception.
- Accurate assessment using tools.
- Determine etiology, if possible.
- Assess medication usage and effectiveness.
- Assess nutritional needs.

FIGURE 7

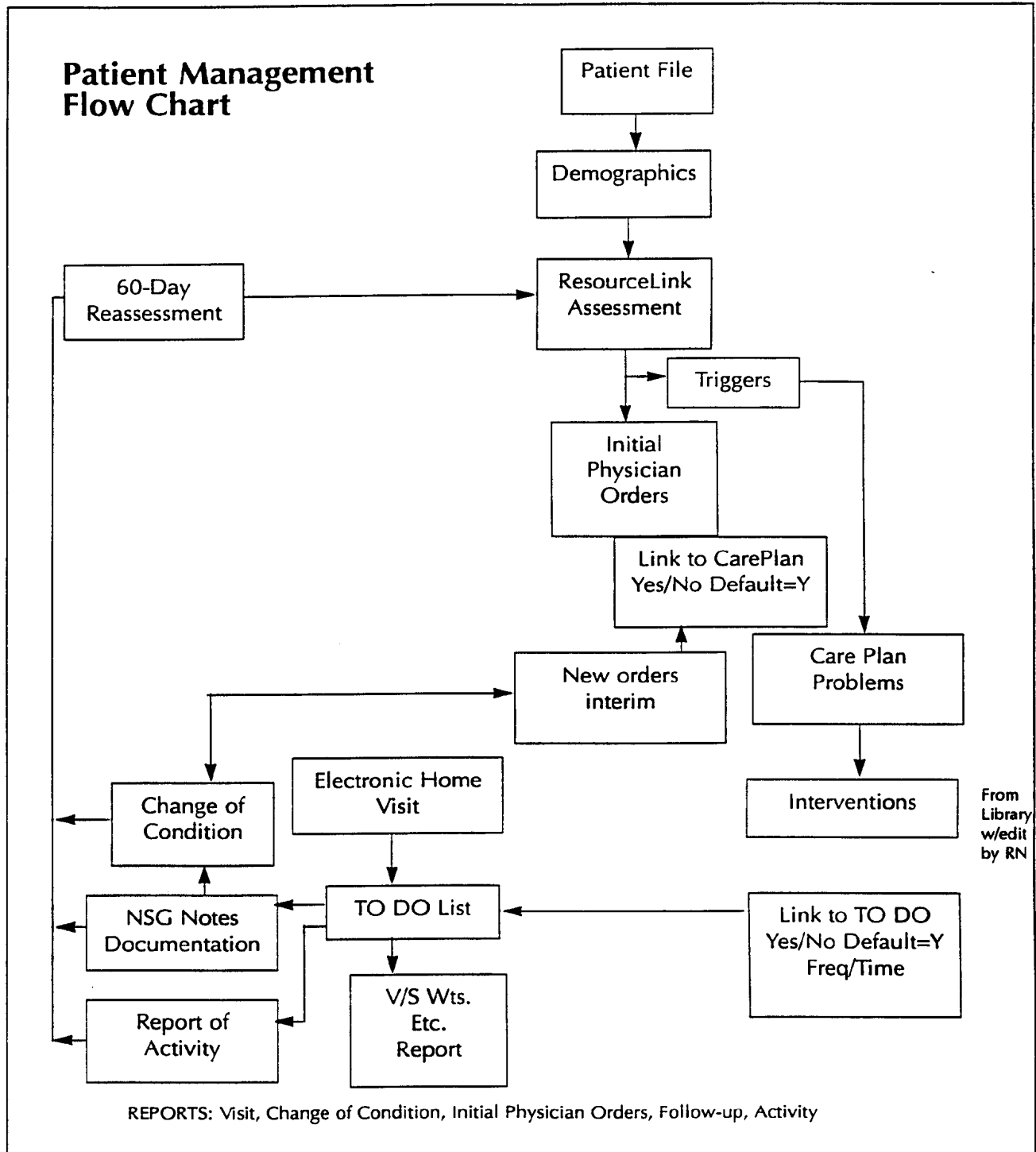
VITALS AND WEIGHTS INFORMATION Close

Select Name: Select ID: 0:00:00 1

| Date | Time | Glucose | SY | DY | Pulse | Resp | Temp | Weight | Height |
|----------|-------|---------|-----|----|-------|------|------|--------|--------|
| 3/7/96 | 17:23 | 46 | 112 | 54 | 66 | 12 | 96 | 130 | 62 |
| 4/11/96 | 12:14 | 46 | 112 | 54 | 66 | 12 | 96 | 130 | 62 |
| 5/15/96 | 08:13 | 60 | 90 | 50 | 72 | 12 | 97.8 | 130 | 61 |
| 10/24/96 | 14:20 | | 130 | 50 | 66 | 10 | 97.8 | | |

Monitoring Stats **Add** **Edit** **Save** **Cancel** **Done**

| | |
|----------|------|
| 10/24/96 | 66 |
| 14:20 | 10 |
| | 97.8 |
| 180 | |
| 50 | |



12/12

FIGURE 9

| | | | |
|------------------|-----------------------------|-------------------------|--------------|
| Date: 10/24/1996 | Current Plan of Care | | Facility 001 |
| Time: 8:17 am | | | Page 1 of 4 |
| User: | Current Items Only | All Categories Included | |

Resident ID: Gender: F DOB:
 Admit Date: 4/3/96 Room/Bed: SSN: 000-00-0000
 Physician: , CP Review Date:
 Primary Dx: 198.5 Cancer bone, secondary site

| Cat /Cond /Outc /Intervention | Date Identified | Date Resolved | Item's Next Rev. Date | Discipline |
|-------------------------------|-----------------|---------------|-----------------------|------------|
|-------------------------------|-----------------|---------------|-----------------------|------------|

Gastrointestinal

4/18/96

Alteration in health maintenance, as evidenced by evidenced by abdominal discomfort related to r/t duodenal ulcer

4/18/96

Patient will be free of digestive discomfort over next 60 days

4/18/96

Cimetadine 400mg po BID

4/18/96

ALL

assess for any increased discomfort and any signs of rectal bleeding report any to MD

4/18/96

ALL

assess for changes in activity level

4/18/96

Pain / Comfort

4/11/96

Activity intolerance, as evidenced by evidenced by complaints of pain and fatigue related to IgA Myeloma

4/18/96

patient will be able to do own ADL's and have no acute discomfort over next 3 months

4/18/96

[Acetaminophen with Codeine] Tablet # 3

4/18/96

ALL

Evaluate coping skills

4/18/96

ALL

[] Roxicet 1 po q 4 hrs prn pain

7/30/96

ALL

[] Relafen 750 1 po q 12 hrs

7/30/96

ALL

Alteration in comfort

4/11/96

patient will be able to do own ADL's and have no acute discomfort over next 3 months

4/11/96

Use numerical or visual analog scale

4/11/96

ALL

Asses use and effectiveness of medications as ordered for pain

4/11/96

RN

Teach appropriate balance of rest and activity

4/11/96

ALL

INTERNATIONAL SEARCH REPORT

 International application No.
 PCT/US97/20538

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : G06F 17/60, 17/40, 13/362

US CL : 128/903, 904; 379/106.02; 600/301; 705/2

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 705/2; 379/106.02

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS, Dialog

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| Y | US 5,441,047 A (DAVID ET AL.) 15 August 1995, columns 5-20. | 1-7,10 |
| Y | US 5,390,238 A (KIRK ET AL.) 14 February 1995, abstract, columns 1-6. | 1,2,4,5,10 |
| Y | US 5,339,821 A (FUJIMOTO) 23 August 1994, abstract, columns 2-9. | 1,2,4-7 |
| Y | US 5,077,666 A (BRIMM ET AL.) 31 December 1991, columns 1-11. | 2,8 |
| Y | US 4,838,275 A (LEE) 13 June 1989, columns 2-23. | 1-3,5-7,9,10 |
| Y | US 4,732,411 A (SIEGEL) 22 March 1988, entire document. | 8,9 |



Further documents are listed in the continuation of Box C.



See patent family annex.

| | |
|---|--|
| * Special categories of cited documents: | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
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| "E" earlier document published on or after the international filing date | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" document member of the same patent family |
| "O" document referring to an oral disclosure, use, exhibition or other means | |
| "P" document published prior to the international filing date but later than the priority date claimed | |

Date of the actual completion of the international search

29 JANUARY 1998

Date of mailing of the international search report

10 MAR 1998

 Name and mailing address of the ISA/US
 Commissioner of Patents and Trademarks
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/20538

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| Y | MOWRY, MYCHELL M ET AL. Evaluating Automated Information Systems, Nursing Economics, vol 5, no 1, January/February 1987, entire article. | 1,2 |